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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

Applicant: Marvin L. Schilling et al

Serial No: 09/964,120

Filed: 09-25-2001

For: Method for Producing Biologically Active Products

Group Art Unit: 1616 Examiner: Sharmila S. Gollamudi

Hon. Commissioner of Patents
& Trademarks,
Washington, D.C. 20231

Appellant's Brief

Applicants in the subject application herewith appeal from the decision of the Examiner finally rejecting claims 1-17. In accordance with the provisions of 37 CFR 1.192 appellants state:

(1) Real Party. That they, the inventors, Marvin L. Schilling and Richard D Fafard are the real party in interest.

(2) Related Matters. There are no other appeals or interferences known to appellant relating to the subject matter of this application.

(3) Status of Claims. Claims 1-17 are pending in this appeal, a copy of which is attached hereto.

(4) Status of Amendments. Appellant has filed responses subsequent to the final rejection in order to overcome the procedural objections which amendments have

been entered and which have removed such objections. These amendments are stated not to have overcome the rejections based on art.

(5) Summary of Invention. This invention relates to a method of thermally dehydrating food products and more specifically proteinaceous food products under conditions that will prevent denaturization and retain the original organic structure of such materials and particularly the biologically active components of comminuted food products through the use of low temperatures and in the presence of an ionic salt and an antimicrobial agent.

(6) Issues. (1) The rejection of the claims 1-16 as unpatentable under 35 USC 103 over Ericcson (US 5,733,241) in view of Moore (US 5,645,851) or Maret (US 3,878,197). (2) The rejection of Claims 1-2, 4-6, 12 and 15-17 as unpatentable under 35 USC 103 over JP 359088065 in view of Ueno et al (US 4,789,497).

(7) Grouping of Claims. The rejections are applicable to the entire group of claims on appeal.

(8) Argument.

As already pointed out the process of the present invention relates to the thermal dehydration of food products and particularly proteinaceous materials such as bone cartilage (not the bone itself which has a different structure) in the presence of an antimicrobial agent and an ionic salt at temperatures below which denaturization occurs. The denaturization is defined as any change the original organic structure of the material being dehydrated. The dehydration is conducted until the water content is reduced so that it is no longer subject to pathogenic contamination during a period of commercially attractive shelf life. Claim 3 sets forth the conditions and concentrations in numeric form which will lead to such results. As is pointed out in the Moore patents cited by the applicants (page 1, line 25 to page 2, line 3), proteins have an insoluble structure that helps to retain the beneficially active ingredients, which would be lost if the product is extracted

since extraction involves solution of components. Both the original product, and the extracted product have been modified. Similarly other forms of treatment such as heating to sterilization temperatures will also cause denaturization and a reduction or loss of the beneficial components of the product heated.

Claims 1-16 have been rejected under 35 USC 103(a) as unpatentable over Ericsson et al (US 5,733,241) in view of Moore (US 5, 645,851) or Maret (US 3,878,197) and as unpatentable under 35 USC 103 over JP 3590088-65 in view of Ueno et al (US 4,789,497). It is submitted that in the proceedings below the examiner misconstrued the references, interpreting them out of context to support an argument of obviousness and used applicants teaching to supply the links missing in the art. When properly construed the references fail to support the examiner's position.

The examiner in his final rejection correctly argues the primary references as relating to extraction. However applicants' process is not one of extraction but a dehydration. Extraction is exactly what applicants want to avoid because it destroys or decreases the potency of the beneficial organic components of the material being dehydrated. Dehydration is defined as simply the removal of water whereas extraction is defined in chemical dictionaries (e.g., "Condensed Chemical Dictionary, 1966, Reinhold Publishing) as follows:

> "A process in which one or more components are removed from a liquid mixture with a second solvent which itself is nearly insoluble in the first. In other cases the second liquid may dissolve, i.e. extract, from the first liquid the component that is to be purified and leave the associated impurities in the first liquid."

Thus to be an extraction, the process must involve the removal of one or more components from the original mixture using an extraction solvent in which the desired material to be extracted is dissolved. The process claimed by applicants does not involve the use of an extraction solvent and does not involve the removal of any components of the original starting material by solution in such extraction solvent. Applicants' process

is not an extraction process, it is a dehydration process in which water is removed by vaporization and not through the use of a solvent or through mechanical means. Furthermore no solid components are in any way modified by the dehydration process. In applicants' process the organic substance is treated with aqueous solutions to add components such as the antimicrobial agent and the ionic salt without the removal of any components other than water.

Bearing the difference of extraction and dehydration in mind it is submitted that applicants' claims are not obvious over Ericcson (US 5,733,241) in view of Moore (US 5,645,851) or Maret (US 3,878,197). In the final rejection the examiner states:

> "Ericcson discloses the method of preparing bioactive extracts. The reference also teaches the method of extracting active agents from plant material or animal material." (Emphasis added)

The examiner is absolutely correct. Ericsson indeed discloses an extraction process. Thus the organic substance in Ericsson is treated with an extraction solvent to remove the desired active components (column 1, lines 43-48) and not only that the material is then subjected to fermentation (column 1, lines 48-51) which further modifies the chemical structure of the original material. The preferred extracting agents, and the only ones exemplified are organic solvents such as ethanol, or other alcohols and aqueous mixtures of such. Even where the reference suggests the use of an aqueous extracting agent, Ericsson states that the initial organic substance is treated with heating and/or stirring "until the solids are dissolved" (column 4, lines 25, 26). This is the antithesis of applicants' process, which retains the organic substance in its original insoluble state.

The examiner states that Ericsson macerates the product and distills the product with ethanol. The Examiner's characterization of Ericsson clearly supports applicants' arguments that applicants' process is very different. Applicants' process does not involve the use of a separate solvent, which dissolves part of the product in such solvent, i.e. extracts it, and then recovers the extracted product through distillation. The Examiner

points out that the plant materials yield essential oils. However the Examiner fails to consider that the essential oils are separated from the extracted product before it is submitted to fermentation.

The examiner argues that Ericsson teaches reducing the moisture content to less than 14 % (column 2). This drying step is performed on the raw product before it is comminuted and before it is exposed to an extraction solvent, which is the actual process claimed in Ericsson. The drying step is performed to provide the starting material with shelf life and there is no suggestion that low temperature drying preserves the structure of the starting material. This dehydration is done in the absence of an ionizable salt or antimicrobial agent. There is no suggestion for such, and on the contrary the teaching is that dehydration at the indicated temperatures is sufficient to provide stability and thus leads away from applicants' process. The fact that the subsequent extraction and separation steps may include additives has no bearing on the drying process and can only be imputed to such through applicants' teaching. The temperature range of 100 to 140^0 F suggested for the drying process does not suggest an upper limit of 110^0 F as called for by claim 3 and would lead to denaturization which would destroy much of the benefits provided by applicants process.

The examiner points to the fact that Ericsson in column 4, lines 20 to 24, shows the use of an extracting solution containing NaCl and KCl and this argument is repeated in the subsequent advisory action. It is pointed out that the formulas in the reference do not show a chloride but a carbon iodine compound. It is not clear from the copy submitted to applicants that these formulas are a typographical error. However regardless of whether it is or not, the alleged "chlorides" are used as part of the extraction solvent and removed with the extracted materials dissolved in the extraction solvent. It is not retained in the original material and thus not a stabilizer for such.. Again the examiner relies on a teaching applicable to an extraction and not a dehydration. In applicants' case the salt becomes part of the product and is retained after dehydration in the solid insoluble product. No such use is suggested by the reference.

The examiner argues that Ericcson in column 4, lines 40-50 suggests the use of low temperatures to avoid denaturization. This particular step relates to an intermediate step in Ericcson, i.e., the handling of the product after the initial extraction and before fermentation. Thus it involves product that has been extracted by solution from the original material and therefore no longer has the original insoluble structure. More specifically the step referenced by the Examiner relates to the removal or extraction of oils that were formed in the original extraction process and thus is a still further separation using vacuum or steam distillation and does not involve the dehydration of even the extracted product. In such a separation Ericcson suggests that it might be beneficial not to raise the temperatures above 80^0 C because proteins may be destroyed at that temperature as would the use of high alcohol concentration in the extraction solvent. Thus Ericcson contains no suggestion that his extraction itself destroys or reduces the activity of components contained in the original material.

In summary therefore there is no suggestion of applicants' dehydration process which requires retention of the original structure in unextracted form and the dehydration at temperatures below denaturization in the presence of stabilizers. The examiner's arguments improperly singles out parts of the teachings of the reference without considering such in the overall context of the teachings of the reference. A fair consideration of the reference fails to suggest applicants' process.

Moore, the secondary reference discloses product of the type corresponding to that made by applicants' process and points out the problem of extracting proteins as destroying the insoluble original structure of the material and the simultaneous loss of active ingredients (column 2, lines 6-21 and column 3, lines 18-35). Moore discloses drying the product at temperatures below 110^0 F to reduce the water content. Even though the drying process used by Moore may be adequate for small quantities of concentrated biologically active materials, it is not suited to large-scale production of materials that retain their original structure. In order to achieve such it is necessary to provide stabilizers in the process. Applicants' process of conducting the dehydration in the presence of significant concentrations of an ionizing salt allows dehydration on a

large scale without causing the beneficial components of the organic product being dehydrated to change. Thus in the case of collagen II containing materials applicants' process retains the collagen II in its crosslinked, water-insoluble form. Moore adds nothing to the initial drying step disclosed in Ericsson. Neither suggests the use of an ionizing salt to stabilize the dehydration.

The combination of Ericsson with Moore is deemed to be improper since Ericsson is directed to an extraction process involving solution of the active ingredients, whereas Moore teaches that the use of an extraction process destroys the original structure of the collagen II and is therefore undesirable. The argument used to reject applicants' claims as unpatentable over Ericsson in view of Moore is not supported by the actual teachings of the references and the rejection should be reversed.

The other secondary reference, Maret, relates to the extraction of components contained in aloe gel after removal of the hulls from the leaves. The desired components in the resulting gel are extracted by reacting the gel with a solution containing citric acid, ascorbic acid glycine and phosphoric acid using ultraviolet light. As disclosed in column 3, lines 1-12, the process involves a stereochemical polymerization of the ingredients contained in the aloe extract catalyzed by UV radiation. Thus, there is a substantial change in the chemical structure of the extract. Any relationship to applicants' process is tenuous at best. The process of the reference is an extraction and not a dehydration. The chemical components of the original organic substance are drastically changed by means of a chemical reaction exactly the thing that applicants' process prevents. The amount of KCl used in the extraction solution is minimal and does not act as a stabilizer for the remaining insoluble product. Thus Maret adds nothing to the teachings of Ericsson to bring such closer to applicants' claimed invention.

Claims 1-2, 4-6, 12 and 15-17 also been rejected under 35 USC 103(a) as unpatentable over the Japanese abstract (JP 359088065) in view of Ueno (US 4,789,497).

The abstract discloses a process in which comminuted bone and marrow of animals is combined with a solution of lecithin and a solution of sodium hypochlorite and then further pulverized to an ultra-fine powder under temperature conditions to prevent the thermal denaturation of proteins. In a separate and subsequent step the powder is washed and then dehydrated to the "proper water content", however the reference fails to disclose what the proper water content is. The reference states that the pulverization of bone material is done at thermal conditions which prevent denaturization. There is no teaching that the same limitation applies to the dehydration. The dehydration is not defined in terms of either conditions or result and in the absence of such there is no basis to conclude that the dehydration contemplated involves any protection against denaturization. Furthermore although the reference discloses the use of sodium hypochlorite, i.e. an antimicrobial agent, in the pulverization there is no teaching of such use in the dehydration step. Since the product is washed with water before it is dehydrated, there is no basis to assume that the hypochlorite used in the pulverization step is carried over into the dehydration step.

By itself the phrase "dehydrating to a proper water content" is meaningless. Neither method nor result is specified. The method could be merely draining the water off. There is no disclosure that the pulverized bone is heated. The proper water content could very well mean the water content of the original material is retained and that the only water removed is that of the added solutions, such removal would not prevent adverse microbial and pathogenic activity.

The reference therefore fails to disclose or suggest that the dehydration involves a thermal dehydration and specifically a thermal dehydration without denaturization. There is no suggestion that sufficient water is removed to prevent microbial or pathogenic activity. The water removed in applicants' process is that of the original product and not that of any added solution. There is no teaching of the use of an antimicrobial agent in the dehydration. Furthermore as the examiner concedes the reference fails to disclose the use of an ionizing salt. The examiner has imputed details to the vague process of the reference taken from applicants' teachings to support the

rejection. It is submitted that such constitutes an improper extension of the reference and voids the rejection.

The secondary reference, Ueno, relates to dehydrating fish meat by mechanical means to produce a food product. The mechanical means employed are compression methods that squeeze out the water such as a sieve and a screw press (see examples). As is apparent from column 1, lines 14-43, the dehydration involved is that of water retained by the fish meat after being washed. The dehydration is carried out in the presence of both calcium or magnesium chloride and sodium chloride. The divalent calcium and magnesium salts are added to improve the dehydration process, however such addition causes denaturization due to the presence of calcium and magnesium ions. The denaturization is that of the mechanical properties of the fish meat defined as "ashi" (column 1, lines 61-68). To prevent that type of denaturization the patent teaches the use of both sodium chloride and magnesium or calcium chlorides.

Applicants submit that there is no basis for the combination of this reference with the Japanese abstract. They relate to different materials, different dehydration processes and different denaturization effects during dehydration. Thus if there is any teaching of denaturization during dehydration in the Japanese abstract, which applicants contest, it is that due to heating and is chemical in nature. The denaturization of the secondary reference is that due to the presence of calcium and magnesium ions and involves the mechanical properties of the product.

However even if the combination is deemed to be proper the secondary reference only extends the teaching of the primary reference with respect to a mechanical dehydration involving a denaturization of mechanical properties. There still is no suggestion that the dehydration should be carried out by thermal means under conditions that prevent chemical denaturization. Additionally the only water removed in the combination of the two references is that of water added as a result of the washing of the material, and not any water. There further is no suggestion of the use of an antimicrobial agent.

The combination of the Japanese abstract with Ueno fails to suggest the use of a thermal dehydration, sufficient to prevent decomposition as a result of microbial or pathogenic activity, in the presence of both an antimicrobial agent and an ionizable salt under conditions in which the original structure of the beneficial agents is retained in the dehydrated product.

Although all of applicants' dependent and subsidiary claims are believed to be patentable in view of the foregoing arguments, there are additional reasons why such claims are patentable.

Thus claim 2 is deemed to be additionally patentable over the combination of the Japanese abstract and Ueno since neither of the references suggests the addition of the ionizing salt in solid form, an important feature considering the low moisture content desired. In both references the salts are added in the form of solutions. In Ericcson and Moore there is not even a suggestion of the use of any salt in the dehydration step.

Claim 3 limits the process to a product having a water content of less than 15 % and an ionizable salt concentration of at least 15 %. Ericsson suggests such a water content but fails to suggest the use of an antimicrobial agent and a salt concentration of at least 15 % by weight. The combination of the Japanese abstract and Ueno fails to suggest dehydration to 15 % and the use of an added ionic salt of 15% or more. The lowest water contents suggested by the combination are found in the examples of Ueno and are at least 70 % and the concentration of the added salts is stated to be in the range of 0.05 to 1.0 % of the solution added (claim 1), which even if totally incorporated into the fish meat is still less than 2 %, since the weight of the solution added is about twice that of the fish meat according to the examples. Furthermore claim 3 is deemed to be patentable over the combination of the Abstract and Ueno because none of the references teaches an upper temperature limit of 110^0 F in the dehydration to less than 15%.

For the same reasons as set forth with respect to claim 3, claims 15-17 are deemed to patentable over the combination of the Abstract and Ueno. However in addition the claims 15-17 are further deemed to be patentable because neither reference suggests the dehydration of cartilage and more specifically chicken cartilage. Thus the Abstract relates to the pulverization of bone and marrow, which is not cartilage and very different in chemical composition and Ueno relates to the mechanical dehydration of fish meat.

Applicants submit that they have demonstrated the patentability of the claims on appeal. The examiner's attempt to apply teachings relating to extraction methods in Ericcson to dehydration methods is flawed and improper. The two are fundamentally different. However even when combined such methods fail to suggest the elements of applicants' process. The implementation of the vague and indefinite teachings of the Japanese abstract with the Ueno reference fails to suggest applicants' process in that Ueno does not involve a dehydration through heating.

Applicants request that the examiner's rejection be vacated and the claims be held allowable.

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Certificate under 37 CFR 1.8

I hereby certify that two copies of the foregoing brief together with a check for the necessary fees is being deposited with the United States Postal Service by priority mail in an envelope addressed to the Commissioner of Patents & Trademarks, Washington D.C., 20231 as of the date set forth below.

Date: 1/18/03

Signature _____
Bernd W. Sandt

Appendix to Appeal Brief

APPEALED CLAIMS

1. A method for the dehydration of naturally occurring organic substances containing biologically active components, which comprises, combining such substances with an antimicrobial agent and an ionizing salt, heating the resulting mixture in particulate form at a temperature below which denaturization occurs until the water content is reduced to below which substantial microbial or pathogenic activity occurs, and recovering (a product) the biologically active components of the particulate form in (its) their original natural structure.

2. The process of claim 1 wherein the ionizing salt is used in solid form.

3. A method for the dehydration of naturally occurring consumable substance, which comprises combining such substance with an ionizable salt, in a concentration of at least 15 % by weight of the substance and an antimicrobial agent and heating the resulting mixture in particulate form at a temperature below about 110^0 F until the water content is reduced to below 15 %.

4. The method of claim 1 wherein the process is carried out in the presence of an oxygen containing antimicrobial agent and an ionizable consumable salt.

5. The method of claim 3 wherein the anti-microbial agent is a chlorine- containing compound.

6. The method of claim 3 wherein the substance is a protein.

7. The method of claim 6 wherein the protein is Type II collagen-containing protein.

8. The method of claim 2 wherein the salt is sodium or potassium chloride.

9. The method of claim 4 wherein the dehydration is carried out at temperatures of 100 to 110^0 F.

10. The method of claim 4 wherein the naturally occurring material is a plant species

11.. The method of claim 10 wherein the naturally occurring material is aloe or foxglove.

12. The method of claim 4 wherein the naturally occurring material is from an animal.

13. The method of claim 12 wherein the naturally occurring material is bone cartilage.

14. The method of claim 13 wherein the bone cartilage contains Type II collagen.

15. The method of dehydrating chicken cartilage which comprises comminuting such, soaking the resulting product in an aqueous solution of an antimicrobial agent, blending such with potassium or sodium chloride in a concentration of at least 15 % by weight of the comminuted product and dehydrating the resulting mixture in particulate form at temperatures below 110^0 F until the water content is reduced to below 10%.

16. The method of claim 15 wherein the antimicrobial agent is a hypochlorite.

17. The process of claim 15 wherein the dehydration is carried out in the presence of hydroxypropyl methylcellulose or lecithin.